

**REMARKS**

The amendments to claims 2, 3, and 13 are supported throughout the application as filed, including at pages 13 and 14. New claims 14-17 are also supported throughout the application as filed, including at page 15 (claims 14 and 16), pages 19, 20 and 22 (claim 15), and page 25 (claim 17). Accordingly, the amendments to the claims do not introduce new matter.

This amendment is being filed with a Request for Continued Examination under 37 C.F.R. § 1.114 in response to a final Office Action mailed March 6, 2003 (hereinafter, the "Office Action"). In that Office Action, claim 1-5, 8 and 13 were rejected under the judicially created doctrine of obviousness-type double patenting over claim 108 of U.S. Pat. No. 6,245,740. Claims 1-5, 8 and 13 were also rejected under 35 U.S.C. 112, second paragraph for asserted vagueness in using the terms "solution" and "mixture" interchangeably, resulting in a perceived lack of clarity as to the "physical form of G-CSF/glycerol composition . . . intended by the claims." Office Action at pages 3-4.

In an amendment forwarded September 5, 2003, Applicant attached a duly executed terminal disclaimer, effectively overcoming the rejection of claims 1-5, 8 and 13 under the judicially created doctrine of obviousness-type double patenting over claim 108 of U.S. Pat. No. 6,245,740. Accordingly, that rejection should be withdrawn, and an analogous rejection of any of new claims 14-17 would be improper.

Applicant submits that the sole remaining rejection, the rejection of all pending claims for indefiniteness under § 112, second paragraph, should also be withdrawn. At pages 3-4, the Examiner rejected all claims as indefinite, noting that claims 1 and 8 appear to use the terms "solution" and "mixture" interchangeably. The sole support for this assertion is the Examiner's characterizations of two passages in the instant specification, one assertedly identifying a G-CSF/glycerol "solution," and the other passage apparently addressing a G-CSF/glycerol "suspension." These passages, alone or in combination, fail to support the Examiner's proposition that the terms "solution" and "mixture" have been equated in the instant application. For that reason alone, Applicant submits that the Examiner has not established a *prima facie* case of indefinite claim language and the rejection should be withdrawn.

Of equal importance, the Examiner has focused on the physical form of the composition. The invention as claimed, however, does not depend on the physical form of the composition. Furthermore, the physical form of the composition is an inherent property of the components in the composition, their relative levels in the composition, and the physical properties of the composition (e.g., temperature). There is nothing in the application, or the associated record of prosecution, to establish or suggest that the claimed compositions, and processes for using them, are limited to particular physical forms. For that reason, Applicant has resisted amending the claims. In the present amendment, however, Applicant has expressly deleted the assertedly problematic terms and maintains that the claims as amended are both definite and otherwise allowable. These amendments do not narrow the claimed subject matter, and Applicant has not surrendered any subject matter thereby.

Additionally, Applicant continues to maintain that the terms "solution," "mixture," and "suspension," as previously recited in the claims, are not indefinite. Nowhere in the specification are these terms given special meanings, and the Examiner has not pointed to any such passage(s). In Applicant's prior response forwarded September 5, 2003 (*see* pages 5 and 6, incorporated herein by reference), the ordinary meanings for these terms were provided and Applicant explained that these terms, given their ordinary meanings in the art, did not render any of the pending claims indefinite under the second paragraph of § 112. To expedite prosecution and properly focus attention on the invention being claimed, however, Applicant has amended the claims. Thus, the rejection of claims 1-5, 8 and 13 under 35 U.S.C. § 112, second paragraph, for asserted indefiniteness has been rendered moot-in-part and has been overcome-in-part; accordingly, the rejection should be withdrawn. Moreover, a rejection of any of new claims 14-17 on analogous grounds would be improper.

The Examiner also asserted that claims 1 and 8 were indefinite in reciting a solution of G-CSF without defining those solutions. In response, Applicant notes that the express wordings of the claims recite a "solution of G-CSF." "Solutions of G-CSF" are well-known in the art, as are the corresponding solvents. Because one of skill in the art would know which compositions are G-CSF solvents, there is no indefiniteness in the recitation of a solution of G-CSF. One need not teach, and preferably omits, that which is well-known in the art. Moreover, patent applications are not production specifications. Further, the intended purpose of the claimed subject matter is the preparation of a pharmaceutical

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composition (claim 1) or the performance of a process for preparing such a pharmaceutical composition (claim 8). One of skill in the art would know which G-CSF solvents are suitable for the intended purpose of the claimed subject matter, i.e., a pharmaceutical composition for administration, or the preparation of such a composition. Therefore, one of skill in the art would know the metes and bounds of the claimed subject matter because that individual would know which solvents could be found in the "solution of G-CSF" as recited in the pending claims. Accordingly, the claims would not be indefinite to one of skill in the art, and that is the standard by which indefiniteness is assessed. Thus, the rejection of claims 1 and 8 as indefinite under § 112, second paragraph, for an asserted failure to identify suitable solvents has been overcome and should be withdrawn. Further, a rejection of any of new claims 14-17 on analogous grounds would be improper for the reasons provided above.

For all of the foregoing reasons, the rejection of claims 1-5, 8 and 13 under the judicially created doctrine of obviousness-type double patenting over claim 108 of U.S.P.N. 6,245,740, and the rejection of claims 1-5, 8 and 13 under 35 U.S.C. § 112, second paragraph, for asserted indefiniteness, have been overcome and should be withdrawn. Moreover, corresponding rejections of any of new claims 14-17 would be improper for analogous reasons.

### Conclusion

In view of the preceding amendments and comments, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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